

Readopt with amendment Ph 900, effective 12-4-08 (Document # 9341), to read as follows:

CHAPTER Ph 900 MAIL-ORDER PHARMACY

Statutory Authority: RSA 318:37, II

PART Ph 901 PURPOSE AND SCOPE

Ph 901.01 Scope. The provisions of this chapter shall apply to, and impose duties upon, all mail-order pharmacies holding registrations issued by the board.

PART Ph 902 DEFINITIONS

Ph 902.01 “Mail-order pharmacy” means “mail-order pharmacy” as defined in RSA 318:1, VII-b, namely, “a pharmacy that is located in a state of the United States, other than this state, whose primary business is to dispense a prescription drug or device under a prescription drug order and to deliver the drug or device to a patient, including a patient in this state, by the United States mail, a common carrier, or a delivery service. Mail-order pharmacies include, but are not limited to, pharmacies that do business via the Internet or other electronic media.”

PART Ph 903 REGISTRATION

Ph 903.01 Application.

(a) No person shall conduct or operate a mail-order pharmacy located outside of this state by delivering in any manner prescription drugs or prescription devices into this state unless such pharmacy is registered in New Hampshire and a permit has been issued by the New Hampshire board of pharmacy.

(b) Application form MO-1, “Registration of Mail-order Pharmacy,” may be obtained from and shall be filed at the office of the board, identified in Ph 103.03.

(c) Applicants for registration as a mail-order pharmacy shall submit a completed MO-1 that contains the following information:

- (1) Name, address, telephone number and Internet address, if applicable, of the pharmacy;
- (2) The names, addresses and titles of all principal corporate officers, if incorporated and if unincorporated, partners or owners of the pharmacy;
- (3) If a corporation, a certificate of incorporation from the state in which incorporated;
- (4) If a limited liability company, partnership or sole proprietorship, a tax ID number;
- (5) The name and home-state pharmacist license number of the pharmacist-in-charge of the location listed in number (1) above;
- (6) A copy of the pharmacy’s current license, permit, or registration certificate used by the regulatory or licensing agency of the state in which the pharmacy is located, as well as a copy of the current DEA registration, if applicable;
- (7) A copy of the most recent inspection report conducted by the state in which the pharmacy is located;

- (8) A list of any and all Internet websites from which the mail-order pharmacy solicits business; and
 - (9) Signature of the pharmacist-in-charge and date.
- (f) As attachments to the completed MO-1, the applicant shall provide the following:
- (1) One of the following:
 - a. Verified Internet Pharmacy Practice Sites™ accreditation from the National Association of Boards of Pharmacy®; or
 - b. The following materials:
 - 1. At least 2 photographs of the actual existing exterior, including the pharmacy signage, of the building in which the pharmacy will be or is currently located;
 - 2. At least 2 photographs of the prescription department as viewed by an approaching patron;
 - 3. At least 4 photographs of the prescription department as viewed from the interior, showing the prescription compounding area, refrigerator, water facilities and pharmaceutical inventory storage area; and
 - 4. Scaled drawings of the pharmacy and drug storage area.
 - (2) A prescription label, containing the name, address and phone number of the pharmacy, that would be used on finished prescription products mailed to NH residents;
 - (3) A sample copy of a printed patient medication profile that shall include the following information:
 - a. Name and address of the patient;
 - b. Name, address and DEA registration number of the prescriber;
 - c. Name, strength and quantity of drug dispensed;
 - d. Assigned prescription number;
 - e. Date of original filling; and
 - f. Date of refill(s); and
 - (4) Copies of the following documents:
 - a. A copy of an inspection report, created within the last 12 to 18 months, which documents compliance with the State of New Hampshire board of pharmacy rules regarding sterile compounding of injectable drugs and non-sterile compounding in compliance with the United States Pharmacopeia Chapter 797 and Chapter 795 pursuant to RSA 318:14-a performed by:
 - 1. Your home state's board of pharmacy;
 - 2. Other responsible state or national regulatory agency; or

3. New Hampshire board of pharmacy approved third party entity.

b. A signed attestation by the pharmacist-in-charge stating there is a policy and procedures manual available showing compliance with USP 795 and 797; and

c. A hood certification inspection report completed under dynamic conditions, not at rest, within the last 6 months; and

(5) The prescribed fee which shall be \$1,000.

(g) Failure to comply with any of the provisions of Ph 903 shall result in denial of a permit.

(h) Any person or pharmacy whose pharmacy business fits the definition of a mail-order pharmacy and delivers prescription drugs or prescription devices to New Hampshire residents from more than one out-of-state pharmacy shall register each such pharmacy separately.

PART Ph 904 REGISTRATIONS – CHANGES IN SUPPORTING DATA

Ph 904.01 Reporting Changes.

(a) The mail-order pharmacy to which a registration has been issued shall within 30-days of any change of information supplied in the original application, notify the board.

(b) The notice required pursuant to (a) above shall contain:

(1) Current New Hampshire registration number of the pharmacy;

(2) Name of the pharmacy, old and new, if applicable;

(3) Address of the pharmacy, old and new, if applicable;

(4) Name of the pharmacist-in-charge, old and new, if applicable; and

(5) Name(s), addresses and titles, of new corporate officers, or partners, or owners.

(c) A new registration shall be required for a change of ownership of an established pharmacy to a successor business entity which results in a change in the controlling interest in the pharmacy.

PART Ph 905 REVOCATION AND DENIAL

Ph 905.01 Effect of Revocation and Denial.

(a) The board shall refuse to issue a registration or shall, revoke a registration whenever the board determines that a mail-order pharmacy, its pharmacist-in-charge, owner(s) or corporate officer(s) has, after notice and opportunity for a hearing, except pursuant to (c) below, committed an act such as but not limited to:

(1) Made a materially false representation or withheld material information in connection with obtaining its registration;

(2) Been found guilty of any felony in connection with the practice of pharmacy or distribution of drugs within the past 5 years;

- (3) Made false representations in connection with the practice of pharmacy that endanger or are likely to endanger the health or safety of the public, or that defraud any person;
 - (4) Failed to comply with RSA 318:37, II, the provisions of Ph 900, or both;
 - (5) Based on an investigation of a complaint resulting from the dispensing of prescription drugs or prescription devices to a resident of New Hampshire been found to be negligent:
 - a. By the board of pharmacy of the state in which the pharmacy is located; or
 - b. By the New Hampshire board of pharmacy if the board of pharmacy of the state where the pharmacy is located failed to initiate an investigation of such complaint within 45-days after referral of the complaint from the New Hampshire board of pharmacy; or
 - (6) Been found guilty of any violation of federal, state or local drug law or have entered into any agreement to resolve violations of such.
- (b) A mail-order pharmacy shall notify the board within 15 days of any order or decision by a board of pharmacy, or any other state or federal agency, imposing disciplinary action on the pharmacy. Notwithstanding the provisions of paragraph (a) above, if the license, permit or registration in the state where the pharmacy is located, is suspended or revoked, then the pharmacy's registration in New Hampshire shall, after notice and opportunity for hearing, be suspended or revoked for the same period of time.
- (c) Notwithstanding the above the board shall issue a registration or not revoke if:
- (1) No harm resulted from the actions of the applicant or registrant;
 - (2) There was no intent to violate any provisions of RSA 318;
 - (3) Corrective action has been taken by the registrant;
 - (4) Remunerations have been made to the affected party(s); and
 - (5) The board determines the action is unlikely to occur again.

PART Ph 906 RENEWAL OF REGISTRATIONS

Ph 906.01 Renewal Registrations Required. All mail-order pharmacy registrations shall expire annually on December 31.

Ph 906.02 Renewal Application Where Obtained and Filed. Applications for the renewal of a registration for a mail-order pharmacy may be obtained from, and shall be filed at the office of the board, identified in Ph 103.03 or online.

Ph 906.03 Renewal Application Contents and When Filed. Renewal applications shall be filed with the board in accordance with the following:

- (a) Applications for renewal of a registration for a mail-order pharmacy shall be made on form MO-2 "Application for Renewal of Registration for Mail-order Pharmacy";

- (b) Each applicant shall provide the following documents via fax, mail, or scanned and emailed to the board, or in the case of items (6) and (7) directly on the renewal form, in order for the renewal application to be processed by December 31st:

(1) A copy of an inspection report, created within the last 12 to 18 months, which documents compliance with the State of New Hampshire board of pharmacy rules regarding sterile compounding of injectable drugs and non-sterile compounding in compliance with the United States Pharmacopoeia Chapter 797 and Chapter 795 pursuant to RSA 318:14-a, I performed by;

- a. Your home state's board of pharmacy;
- b. Other responsible state or national regulatory agency; or
- c. New Hampshire board of pharmacy approved third party entity;

(2) A signed attestation by the pharmacist-in-charge stating there is a policy and procedures manual available showing compliance with USP 795 and 797;

(3) A hood certification inspection report completed under dynamic conditions, not at rest, within the last 6 months;

(4) Copy of the pharmacy's current home state pharmacy license/permit;

(5) Copy of the pharmacy's current federal DEA permit if shipping controlled substances;

(6) Name, address, telephone number and Internet address, if applicable, of the pharmacy;

(7) The names, corporate or business addresses and titles, of all principal corporate officers, if incorporated, or all partners or owners of the pharmacy if not incorporated;

(8) The application and the prescribed fee of \$1,000; and

(9) Signature of the pharmacist-in-charge and date.

Ph 906.04 Failure to Comply. Failure to comply with any of the provisions of Ph 906 shall result in non-renewal of the pharmacy permit

PART Ph 907 CONDITIONS OF REGISTRATION

Ph 907.01 Compliance. As conditions of registration, the mail-order pharmacy shall:

(a) Maintain at all times a valid unexpired permit, license, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident;

(b) Maintain in readily retrievable form, records of legend drugs, devices, or both dispensed to New Hampshire patients;

- (c) Supply upon request, any and all information needed by the board to carry out its responsibilities under the statutes and rules pertaining to mail-order pharmacies;
- (d) Provide for a toll-free telephone communication consultation between New Hampshire patients and a pharmacist at the mail-order pharmacy who has access to the patient's records, and ensure that such toll-free telephone number(s) shall be placed upon the label affixed to each prescription container;
- (e) Provide to the board, upon request, a copy of the policies and procedures governing:
 - (1) Normal delivery protocols and times;
 - (2) Any special packaging or procedures used in delivering temperature-sensitive drug products;
 - (3) The procedure to be followed if the patient's medication is not available at the mail-order pharmacy, or if delivery will be delayed beyond the normal delivery time;
 - (4) The procedure to be followed upon receipt of a prescription for an acute illness, which shall include a procedure for delivery of the medication to the patient from the mail-order pharmacy at the earliest possible time, such as courier delivery, or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time; and
 - (5) The procedure to be followed when the mail-order pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mail prescription drugs become available;
- (f) All finished prescription products shipped to New Hampshire residents shall be shipped in tamper-evident envelopes or boxes;
- (g) A mail-order pharmacy shall not dispense or sell to the public, any drug which is adulterated or misbranded;
- (h) A mail-order pharmacy shall supply, upon request from the board, a statement of origin of any specific drug dispensed to a New Hampshire resident; and
- (i) Any mail-order pharmacy shipping finished prescription products into the State of New Hampshire shall use the address, but without the name of the pharmacy, on file with the New Hampshire board of pharmacy as the return address on the labels of any package shipped into the State of New Hampshire. The return address shall be placed on the package in a clear and prominent manner.